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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,219	05/13/2005	Jasti Venkateswarlu	03108/0202223-US0	7317
7278	7590	05/30/2007		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER STOCKTON, LAURA LYNNE	
			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			05/30/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,219	<b>Applicant(s)</b> VENKATESWARLU ET AL.	
	<b>Examiner</b> Laura L. Stockton, Ph.D.	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 5-13, 15-25 and 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 14 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/12/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

**Claims 1-29 are pending in the application.**

### ***Election/Restrictions***

Applicant's election with traverse of Group I (claims 1-4 and 14 - directed to products) in the reply filed on April 3, 2007 is acknowledged. The traversal is on the ground(s) that: (1) the "special technical feature" of Rule 13.2 has been confused with the "common structure" described in MPEP 1858 III.B; and (2) the genus of compounds described by formula (I) as claimed in claim 1 is evidenced to be free of the prior art according to the International Search Report.

This is not found persuasive because, firstly, the entire scope of the compounds of formula (I) has been examined instead of specific variable definitions as indicated in the Restriction Requirement of

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January 3, 2007. Additionally, the products of formula (III), found in instant claim 26, have also been examined. Secondly, the instant claimed inventions lack unity of invention because the claims do not have a common structural feature that defines a contribution over the prior art. Each of the groups set forth in the previous Office Action represents either a separate process or discrete heterocyclic ring system which one skilled in the art which besides sharing no significant structural element, cannot be said to belong to a recognized class of chemical compounds. For example, the products of formula (II) in claim 24 have a patentably distinct heterocyclic ring system than the products of formula (I) in claim 1. Further, the structural feature of formula (II) in claim 24 does not define a contribution over the prior art. See, for instance, the third compound listed under Example 8 in column 5 (line 65) of U.S. Patent 3,481,953. Accordingly, the unity of invention is considered to be

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lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-13, 15-25 and 27-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 3, 2007.

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***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement***

The Examiner has considered the Information Disclosure Statement filed on April 12, 2007.

***Claim Objections***

Claim 14 is objected to for being substantial duplicates of claim 1. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a

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substantial duplicate of the allowed claim. M.P.E.P.

706.03(k).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph  
of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound of formula (I), its tautomeric forms, its stereoisomers, its pharmaceutically acceptable salts and solvates thereof, does not reasonably provide enablement for derivatives, analogs and polymorphs of a compound of formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

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In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

***The nature of the invention***

Applicant is claiming any derivative, analog or polymorph of a compound of formula (I) in claims 1-3 and 14.

***The state of the prior art and the predictability or lack thereof in the art***



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The state of the art is that polymorphs, for example, do not exist for every compound and that there are sometimes more than one polymorph for a compound. The preparation of polymorphs are not considered routine or uncomplicated since there are numerous specific factors, such as reaction conditions and solvents, which must be adhere to in the preparation of any polymorph.

***The amount of direction or guidance present and the presence or absence of working examples***

There is no evidence of record which would enable the skilled artisan in the identification of the derivatives and analogs of the compounds of formula (I), how to make derivatives and analogs of formula (I) or how to make a polymorph of the compounds of formula (I) or even if polymorphs of certain compounds of formula (I) exist.

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***The quantity of experimentation needed***

The nature of the pharmaceutical arts is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities for each of the diseases and disorders instantly claimed. The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to testing all diseases and disorders generically embraced in the claim language, and when faced with the unpredictability of the pharmaceutical art. Thus, factors such as "sufficient working examples", "the level of skill in the art" and predictability, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

***The level of the skill in the art***

Even though the level of skill in the pharmaceutical art is very high, based on the

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unpredictable nature of the invention and state of the prior art and lack of guidance and direction, one skilled in the art could not use the claimed invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 14 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 26, "general" should be deleted since "general" implies compounds outside the scope indicated in formula (I) of formula (III).

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In claim 1, the terms "its derivatives", "its analogs" and "its polymorphs" makes the claim indefinite and therefore, the metes and bounds of the claim cannot be ascertained. See claims 2, 3 and 14 for same.

In claims 1 and 26, there are valence problems when  $R_1$ - $R_{12}$  represent "oxo"  $\{=O\}$  and thio  $\{-S-\}$ .

In claims 1 and 26, the specific derivatives of "carboxylic acid", "sulfonic acid" and "phosphoric acid" (see page 13 of the instant specification starting at line 4) should be added to the claims and therefore, the metes and bounds of the claims can be ascertained.

In claim 1, under the definition of  $R_{13}$  and  $R_{14}$ , "heterocyclalkyl; optionally" should be changed to "or heterocyclalkyl; or".

In claim 1, the phrase "and represents may be either linear or branched carbon chain", at the end of

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the claim, is unclear as to its meaning and/or what it is defining.

In claims 2 and 3, the dash before the "1" in "Claim -1" should be deleted.

In claim 2, an "and" should be added before the last compound listed.

In claim 4, the dash before the "3" in "Claim -3" should be deleted.

Claims must, under modern claim practice, stand alone to define an invention, and incorporation into claims by express reference to the specification is not permitted. Ex parte Fressola, 27 USPQ 2d 1608 (1993). Claim 14 refers to formula (1). It is improper for claims to refer to subject matter not contained therein, even if the subject matter is contained in the specification.

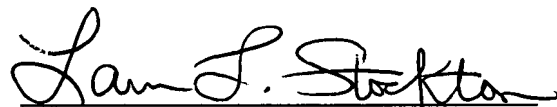
Any inquiry concerning this communication or earlier communications from the examiner should be

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directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, reading "Laura L. Stockton". The signature is fluid and cursive, with the first name "Laura" and last name "Stockton" clearly distinguishable.

Laura L. Stockton, Ph.D.  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

May 29, 2007